

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) A kit comprising firstly a lyophilized didemninn preparation comprising water-soluble material and secondly, and separately contained, a reconstitution solution of mixed solvents, wherein the reconstitution solution of mixed solvents comprises water for injection and a co-solvent.
2. (Previously Presented) A kit according to claim 1, wherein the kit comprises an amount of the lyophilized didemninn preparation that is suitable for the treatment of a tumor in a patient.
3. (Previously Presented) A kit according to claim 1, wherein the didemninn compound is selected from didemnins, dehydrodidemnins, nordidemnins, didemninn congeners and didemninn analogs.
4. (Previously Presented) A kit according to claim 3, wherein the didemninn is aplidine.
5. (Currently Amended) A kit according to any of the preceding claims, wherein the co-solvent is ~~reconstitution solution comprises~~ an alkanol/~~water mix~~.
6. (Previously Presented) A kit according to claim 5, wherein the reconstitution solution further comprises a nonionic surfactant.
7. (Currently Amended) A kit according to claim 6, wherein the nonionic surfactant is 10 to 25% v/v of the solution; the alkanol is ethanol and is 10 to 25% v/v of the solution; and the water for injection is 50 to 80% v/v of the solution.

8. (Currently Amended) A kit according to claim 1, which comprises a vial of lyophilized didemnin preparation comprising a water-soluble bulking agent, and a separate vial of a premix of non-ionic surfactant/ethanol/water for injection.
9. (Withdrawn) A method of preparing a pharmaceutical composition of a didemnin compound, which comprises freeze drying a didemnin/water-soluble additive/alkanol/water mix to provide a lyophilized first component, and separately providing an alkanol/water mix as reconstitution solution.
10. (Withdrawn) A method according to claim 9 wherein the alkanol in the mix is t-butanol.
11. (Withdrawn) A method according to claim 9 or 10 wherein the amount of alkanol in the alkanol/water mix is 25 to 60% v/v.
12. (Currently Amended) A reconstituted pharmaceutical composition comprising:
 - a didemnin compound;
 - a water soluble material;
 - a surfactant;
 - an alkanol; and
 - water for injection.
13. (Previously Presented) The pharmaceutical composition of claim 12, wherein the water soluble material is a water soluble bulking agent.
14. (Previously Presented) The pharmaceutical composition of claim 13, wherein the water soluble water soluble bulking agent is mannitol.

15. (Previously Presented) The pharmaceutical composition of claim 12, wherein the didemnin compound is selected from the group consisting of a didemnin, a dehydrodidemnin, a nordidemnin, a didemnin congener or a didemnin analog.
16. (Previously Presented) The pharmaceutical composition of claim 15, where in the didemnin compound is aplidine.
17. (Previously Presented) The pharmaceutical composition of claim 12, wherein the surfactant is a nonionic surfactant.
18. (Previously Presented) The pharmaceutical composition of claim 17, wherein the nonionic surfactant is Cremophor EL.
19. (Previously Presented) The pharmaceutical composition of claim 12, wherein the alkanol is ethanol.
20. (Currently Amended) The pharmaceutical composition of claim 12, wherein the composition is prepared by the steps comprising:
 - (i) freeze drying a first solution comprising the didemnin compound, the water-soluble material and an alkanol/water for injection mix to provide a lyophilized didemnin preparation; and
 - (ii) reconstituting the lyophilized didemnin preparation with a nonionic surfactant/alkanol/water for injection mix to form a second solution.
21. (Currently Amended) The pharmaceutical composition of claim 20, wherein the alkanol/water for injection mix comprises *t*-butanol.

22. (Currently Amended) The pharmaceutical composition of claim 21, wherein the alkanol/water for injection mix comprises 25 to 60% v/v *t*-butanol.
23. (Currently Amended) The pharmaceutical composition of claim 20, wherein the nonionic surfactant is 10 to 25% v/v of the nonionic surfactant/alkanol/water for injection mix; the alkanol is ethanol and is 10 to 25% v/v of the nonionic surfactant/alkanol/water for injection mix; and the water for injection is 50 to 80% v/v of the nonionic surfactant/alkanol/water for injection mix.
24. (Currently Amended) A lyophilized didemnin preparation prepared by freeze drying a solution comprising a didemnin compound, a water-soluble material and an alkanol/water for injection mix.
25. (Currently Amended) A pharmaceutical composition prepared by reconstituting the lyophilized didemnin preparation of claim 24 with a nonionic surfactant/alkanol/water for injection mix.
26. (Currently Amended) A kit according to claim 1, which comprises a vial of lyophilized didemnin preparation comprising a water-soluble material, and a separate vial of a reconstitution solution of mixed solvents, wherein the reconstitution solution of mixed solvents comprises water for injection and a co-solvent.
27. (Previously Presented) A kit according to claim 1, wherein the didemnin is a dehydrodidemnin.
28. (Previously Presented) The pharmaceutical composition according to claim 12, wherein the didemnin is a dehydrodidemnin.

29. (Withdrawn) An intravenous delivery device having disposed therein: a didemnin compound; a water soluble material; a surfactant; an alkanol; and water.
30. (Withdrawn) A method for delivering a didemnin compound, the method comprising filling an intravenous delivery device with a didemnin compound; a water soluble material; a surfactant; an alkanol; and water.
31. (New) The kit of claim 1, wherein the water for injection is present in an amount sufficient to allow solubilization of the water soluble material, and the co-solvent is present in an amount sufficient to allow solubilization of the didemnin in the lyophilized didemnin preparation.
32. (New) The pharmaceutical composition of claim 12, wherein the water for injection is present in an amount sufficient to allow solubilization of the water soluble material, and the alkanol is present in an amount sufficient to allow solubilization of the didemnin compound.
33. (New) A kit comprising firstly a lyophilized didemnin preparation comprising water-soluble material and secondly, and separately contained, a reconstitution solution of mixed solvents, wherein the reconstitution solution of mixed solvents comprises water and a co-solvent, wherein the water is present in an amount sufficient to allow solubilization of the water soluble material, and the co-solvent is present in an amount sufficient to allow solubilization of the didemnin in the lyophilized didemnin preparation.
34. (New) A kit according to claim 33, wherein the kit comprises an amount of the lyophilized didemnin preparation that is suitable for the treatment of a tumor in a patient.
35. (New) A kit according to claim 33, wherein the didemnin compound is selected from didemnins, dehydroididemnins, nordidemnins, didemnin congeners and didemnin analogs.

36. (New) A kit according to claim 33, wherein the didemninn is aplidine.
37. (New) A kit according to claim 33, wherein the co-solvent is an alkanol.
38. (New) A kit according to claim 37, wherein the reconstitution solution further comprises a nonionic surfactant.
39. (New) A kit according to claim 38, wherein the nonionic surfactant is 10 to 25% v/v of the solution; the alkanol is ethanol and is 10 to 25% v/v of the solution; and the water is 50 to 80% v/v of the solution.
40. (New) A kit according to claim 33, which comprises a vial of lyophilized didemninn preparation comprising a water-soluble bulking agent, and a separate vial of a premix of non-ionic surfactant/ethanol/water.
41. (New) A reconstituted pharmaceutical composition comprising:
a didemninn compound;
a water soluble material;
a surfactant;
an alkanol, wherein the alkanol is present in an amount sufficient to allow solubilization of the didemninn compound; and
water, wherein the water is present in an amount sufficient to allow solubilization of the water soluble material.
42. (New) The pharmaceutical composition of claim 41, wherein the water soluble material is a water soluble bulking agent.

43. (New) The pharmaceutical composition of claim 42, wherein the water soluble water soluble bulking agent is mannitol.

44. (New) The pharmaceutical composition of claim 41, wherein the didemnin compound is selected from the group consisting of a didemnin, a dehydrodidemnin, a nordidemnin, a didemnin congener or a didemnin analog.

45. (New) The pharmaceutical composition according to claim 41, wherein the didemnin compound is a dehydrodidemnin.

46. (New) The pharmaceutical composition of claim 41, where in the didemnin compound is aplidine.

47. (New) The pharmaceutical composition of claim 41, wherein the alkanol is ethanol.

48. (New) The pharmaceutical composition of claim 41, wherein the surfactant is a nonionic surfactant.

49. (New) The pharmaceutical composition of claim 48, wherein the nonionic surfactant is Cremophor EL.

50. (New) The pharmaceutical composition of claim 48, wherein the nonionic surfactant is 10 to 25% v/v of the nonionic surfactant/alkanol/water mix; the alkanol is ethanol and is 10 to 25% v/v of the nonionic surfactant/alkanol/water mix; and the water is 50 to 80% v/v of the nonionic surfactant/alkanol/water mix.